

FEB - 6 1997

Titanium CD HORIZON™ Anterior Spinal System
510(k) Summary
K964623
February, 1997

- I. **Company:** Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
901-396-3133
- II. **Proprietary Trade Name:** Titanium CD HORIZON™ Anterior Spinal System
Classification Name: Spinal intervertebral body fixation orthosis.
- III. The Titanium CD HORIZON™ Anterior Spinal System consists of the following implants components:
- CD HORIZON™ rod (commercially pure titanium), 6.35mm diameter
 - CD HORIZON™ knurled rod (titanium alloy), 6.35mm diameter
 - TSRH® rod (titanium alloy), 6.35mm diameter
 - CD HORIZON™ screws (titanium alloy), 5.5mm, 6.5mm, and 7.5mm diameters
 - CD HORIZON™ Break-Off Set Screw (titanium alloy)
 - CD HORIZON™ Staples (titanium alloy)

The Titanium TSRH® rod can be used with the Titanium CD HORIZON™ Anterior Spinal System. Instrumentation is also available to facilitate implantation of the device components. The Titanium CD HORIZON™ Anterior Spinal System implant components are fabricated from ASTM F136 (or its ISO equivalent) titanium alloy. In addition, the Titanium CD HORIZON™ Anterior Spinal System has a rod fabricated from commercially pure titanium conforming to ASTM F67 or its ISO equivalent. The implant components may be sold sterile or non-sterile. Titanium implants are not to be used with stainless steel implant components in a spinal construct.

- IV. The Titanium CD HORIZON™ Anterior Spinal System is intended to assist in temporarily stabilizing the thoracic and/or lumbar spine until fracture repair or a solid spinal fusion develops. The specific indications for the CD HORIZON™ Anterior Spinal System are the following:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
2. Pseudoarthrosis
3. Stenosis
4. Spondylolisthesis
5. Spinal deformities: scoliosis, kyphosis, lordosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

All components of the Titanium CD HORIZON™ Anterior Spinal System are intended to be fixed/attached to the anterolateral spine by screws/staples in the thoracic and/or lumbar areas only.

- V. Mechanical test data were supplied in support of the Titanium CD HORIZON™ Anterior Spinal System 510(k) notification. The Titanium CD HORIZON™ Anterior Spinal System was declared to be substantially equivalent to other commercially available devices.

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